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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/666,900	09/18/2003	William F. McKay	4002-3376/PC445.00	8517
30565	7590	04/07/2006	EXAMINER	
WOODARD, EMHARDT, MORIARTY, MCNETT & HENRY LLP 111 MONUMENT CIRCLE, SUITE 3700 INDIANAPOLIS, IN 46204-5137			PELLEGRINO, BRIAN E	
			ART UNIT	PAPER NUMBER
			3738	

DATE MAILED: 04/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/666,900

Applicant(s)

MCKAY ET AL.

Examiner

Brian E. Pellegrino

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 December 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-48 is/are pending in the application.
- 4a) Of the above claim(s) 5-11, 13-15, 20-26 and 28-30 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 12, 16-19, 27 and 31-48 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 18 September 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>4/22/04, 8/25/04, 1/31/05</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicant's election of Specie B in the reply filed on 12/19/05 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Claims 10,11,25,26,29,30 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected specie, there being no allowable generic or linking claim. Additionally, claims 5-8,20-23 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected specie, since they read on Specie C—Fig. 11. It was also determined that since Specie A (Fig. 2) was not elected, the claims directed to sub-units disclosed as rolled tissue, claims 9,13-15,24,28 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected specie.

Drawings

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: **75** is recited in paragraph three page 19 to be in Fig. 10. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the

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sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

The disclosure is objected to because of the following informalities: On page 19 of the specification, first full paragraph, the reference characters "72" and "73" have both been used to designate drawstring.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 38 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 38 recites the limitation "said drawstring" in line 1 of the claim. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-3,16-18,39-41 are rejected under 35 U.S.C. 102(e) as being anticipated by Muhanna (6936070). Muhanna discloses that natural tissue, such as pericardium can be used as an intervertebral implant, col. 4, lines 35-37,51-54. Regarding claim 16, Muhanna also discloses a method to repair all or part of the disc by inserting in the intervertebral disc natural tissue, col. 6, lines 34-40,59-62. Muhanna additionally discloses various components or materials are interchangeable within the concept of the invention, col. 7, lines 27-30. With respect to claim 39, Fig. 3A shows a folded configuration of the implant material **14** with a drawstring **15** attached to the implant material. Fig. 4B also shows the implant material with a folded configuration that is implanted in the vertebrae. Please note the functional recitations (in claims 40,41) “for folding” and “in a manner to facilitate folding” have not been given patentable weight because the functional recitations must be supported by recitation in the claim of sufficient structure to warrant the presence of the functional language.

Claims 1,2,12,16,17,27,31,35,36,39 are rejected under 35 U.S.C. 102(e) as being anticipated by Trieu (6620196). Figs. 7A-7C show a braided length of implant material. Trieu discloses a method to replace partially or fully the natural disc nucleus, col. 4, lines 31-34. Trieu also discloses the material for the implant is natural tissue, col. 6, lines 52-54,62-64, col. 7, lines 7-11. Trieu additionally discloses the braided fibers are used for the implant material, col. 7, lines 49-51. Trieu also discloses surfaces (Figs. 14A-14H) can be modified such that it provides the capability to adhere or attach to bone, col. 7, lines 53-65.

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Claims 1,2,12,31,34 are rejected under 35 U.S.C. 102(b) as being anticipated by Laboureau (FR 2651994). Laboureau discloses (abstract) that natural tissue (collagen) is braided to form a prosthetic device to replace an anatomical structure. Please note the intended use carries no weight in the absence of any distinguishing structure. Fig. 5 shows at least three strands are braided together.

Claims 1,2,4,12,16,17,19,31,33-35 are rejected under 35 U.S.C. 102(b) as being anticipated by Sybert et al. (2002/107570). Sybert et al. discloses that natural tissue (small intestine submucosa) can be used to form a prosthetic device, paragraph 31.

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Fig. 3B shows at least three strands of braided tissue and a looped end that enables attachment to bone. Fig. 6 shows the braided device 8 is implanted within the vertebrae.

Claims 1-3,12,31,32 are rejected under 35 U.S.C. 102(e) as being anticipated by Richter (6736838). Richter discloses braided natural tissue, such as pericardium used as an implant, col. 4, lines 13-17,31-35. Please note the intended use carries no weight in the absence of any distinguishing structure.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 36-38,42,44-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stone (5258043) in view of Sybert et al. (2002/107570) and Li (6733505). Stone discloses a woven (col. 5, line 48) spinal implant (Fig. 5A) that is made of natural tissue, col. 6, lines 9-11. However, Stone fails to disclose the implant material is braided and delivered in a folded state. Sybert does teach an alternative tissue material, such as submucosa, paragraph 31. Sybert et al. teach (Fig. 8) that the spinal implant is braided, paragraph 76. Li teaches (Figs. 1,7,8) that spinal implants have drawstrings attached at least three sites (outer length) to fold the implant and aid in insertion of the device between the vertebrae. Li also shows (Fig. 6b) the folded

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configuration enables the device to be delivered in a smaller profile. It would have been obvious to one of ordinary skill in the art to modify the implant formation to be braided as taught by Sybert et al. with the implant of Stone and to incorporate drawstrings as taught by Li such that the implant can be folded for delivery through a cannula.

Regarding claims 42 and 48, it would have been an obvious matter of design choice to modify the length-to-width ratio to be 5:1, since applicant has not disclosed that using this ratio provides any advantage, or solves a stated problem, or is used for any particular purpose. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the implant length-to-width ratio taught by Stone as modified by Sybert and Li or the claimed 5:1 ratio in claim(s) 42,48 because both spinal implants perform the same function of replacing and supporting the existing vertebrae and being able to be delivered in a reduced profile. With respect to claims 46,47, it would have been an obvious matter of design choice to modify the number of attachment sites for drawstrings, since applicant has not disclosed that using a greater number of drawstrings provides any advantage, or solves a stated problem, or is used for any particular purpose. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the implant attachment sites taught by Stone as modified by Sybert and Li or the claimed five sites and ten sites respectively in claim(s) 46,47 because both spinal implants are capable of being drawn and folded to be delivered in a reduced profile with any number of sites for the drawstring.

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Claim 43 is rejected under 35 U.S.C. 103(a) as being unpatentable over Stone '043 in view of Sybert et al. (2002/107570) and Li '505 as applied to claim 42 above, and further in view of Muhanna '070. Stone in view of Sybert and Li is explained as before. However, Stone as modified by Sybert and Li fail to disclose the tissue is pericardium. Muhanna is explained supra. It would have been obvious to one of ordinary skill in the art to utilize pericardium as taught by Muhanna with the spinal implant of Stone as modified by Sybert and Li since it is known to be durable and readily available.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian E. Pellegrino whose telephone number is 571-272-4756. The examiner can normally be reached on M-Th (7:30am-5pm) and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

TC 3700, AU 3738

A handwritten signature in black ink that reads "Brian E. Pellegrino". The signature is written in a cursive, flowing style.

BRIAN E. PELLEGRINO
PRIMARY EXAMINER